

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Members Representing Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health.

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees. Therefore, the agency encourages nominations for appropriately qualified candidates from these groups.

DATES: Industry organizations interested in participating in the selection of a nonvoting member to represent industry for vacancies listed in this notice must send a letter to FDA by *[insert date 30 days after date of publication in the **Federal Register**]*, stating their interest in one or more panels. Concurrently, nomination materials for prospective candidates should be sent to FDA by *[insert 30 days after date of publication in the **Federal Register**]*. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

ADDRESSES: All letters of interest and nominations should be sent to Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and

Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 114, e-mail: *KLW@CDRH.FDA.GOV*.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 114, e-mail: *KLW@CDRH.FDA.GOV*.

SUPPLEMENTARY INFORMATION: Section 520(f)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry.

FDA is requesting nominations for nonvoting members representing industry interests for the vacancies listed below:

Medical Device Panels of the Medical Device Advisory Committee	Approximate Date Representative is Needed
Circulatory System Devices Panel	July 1, 2005
Ear, Nose, and Throat Devices Panel	Nov. 1, 2004
Immunology Devices Panel	Mar. 1, 2005
Medical Devices Dispute Resolution Panel	Oct. 1, 2004
Neurological Devices Panel	Dec. 1, 2004
Obstetrics and Gynecology Devices Panel	Feb 1, 2005
Orthopaedic and Rehabilitation Devices Panel	Sept. 1, 2004

I. Functions

The functions of the medical device panels are listed as follows: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5)

review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Act; (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Selection Procedure

Any organization in the medical device manufacturing industry wishing to participate in the selection of a nonvoting member to represent industry on a particular panel should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association, or firm who is willing to participate in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing on a particular device panel. If no individual is selected within the 60 days, the Commissioner may select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may nominate themselves or an organization representing the medical device industry may nominate one or more individuals to serve as

nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the panel of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations that have expressed interest in participating in the selection process for that panel.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 24, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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